DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–0459]

Indirect Food Additives: Adjuvants, Production Aids, Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of isopropyl laurate in surface lubricants used in the manufacture of metallic articles intended for contact with food. This action is in response to a petition filed by Exxon Co. International.

DATES: This regulation is effective (*insert date of publication in the* **Federal Register**); submit written objections and requests for a hearing (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 18, 1999 (64 FR 13431), FDA announced that a food additive petition (FAP 9B4647) had been filed by Exxon Co. International, 200 Park Ave., Florham Park, NJ 07932–1002. The petition proposed to amend the food additive regulations in § 178.3910 *Surface lubricants used in the manufacture*

of metallic articles (21 CFR 178.3910) to provide for the safe use of isopropyl laurate in surface lubricants used in the manufacture of metallic articles intended for contact with food.

The March 18, 1999, filing notice for the petition stated that the action resulting from the petition qualified for a categorical exclusion under 21 CFR 25.32(i). This conclusion was not correct. Upon further review, the agency determined that such a categorical exclusion is not appropriate for this proposed action, because the lubricant does not remain with the finished food packaging material through use by the consumer. Consequently, as discussed below, the agency considered the environmental effects of this action.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 178.3910 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the* **Federal Register**), file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3910 is amended in the table in paragraph (a)(2) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

* * * * *

(a) * * *

(2) * * *

List of substances	Limitations
* * * *	* * * *
Isopropyl laurate (CAS Reg. No. 10233–13–3).	For use at a level not to exceed 10 percent by weight of the finished lubricant formulation.
* * * *	* * * *

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Dated: 8/20/99
August 20, 1999

L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives

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